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s/ Rachel Potash  
Rachel Potash

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re the Application of:  
**CAROLYN PETERSEN, ET AL.**

Serial No.: 10/776,568

Confirmation No.: Not yet assigned

Filed: February 10, 2004

For: **METHOD OF TREATMENT WITH  
NELFINAVIR**

Group Art Unit: Not Yet Assigned

Examiner: Not Yet Assigned

Honorable Commissioner For Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT**

**UNDER 37 C.F.R. § 1.97(b) or 1.97(c)**

**37 CFR § 1.97(b)**

- ☒ The Information Disclosure Statement submitted herewith is being filed within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d); within three months of the date of entry of the national stage as set forth in § 1.491 in an international application; before the mailing of a first Office Action on the merits; or before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.

**37 CFR § 1.97(c)**

- ☐ The Information Disclosure Statement submitted herewith is being filed after three months of the filing date of a national application other than a continued prosecution application under § 1.53(d); after three months of the date of entry of the national stage as set forth in § 1.491 in an international application; after the mailing of a first Office Action on the merits; or after the mailing of a first Office Action after the filing of a request for continued examination under § 1.114, but before the mailing date of (1) a Final Action under § 1.113; (2) a Notice of Allowance under § 1.311; or (3) an action that otherwise closes prosecution in the application. The Commissioner is hereby authorized to charge the fee as set forth in § 1.17(p) to Deposit Account Number 500329.

- ☐ Applicant requests that the Examiner consider the following copending applications:

Application Serial No.	Filing Date

- ☐ Copies of these copending applications are enclosed.
- ☒ Applicant hereby requests consideration of the Information Disclosure Statement, USPTO form 1449, submitted herewith. Copies of the cited references, except as noted below, are enclosed.
- ☐ This application is a continuation, divisional or continuation-in-part of Serial No. [REDACTED]. Copies of the cited references, if not enclosed, are available in the file of the parent application or parents thereof.
- ☒ This application was filed after June 30, 2003, or entered U.S. national stage under 35 U.S.C. § 371, after June 30, 2003. Copies of U.S. Patents and U.S. Patent Application Publications are not enclosed. (1276 OG 55).
- ☐ Applicant hereby requests consideration of the enclosed International Search Report, which was received in a related international patent application.

The Commissioner is hereby authorized to charge any fee deficiency, including any fee required under 37 C.F.R. § 1.17(p), or credit any overpayment, to Deposit Account Number 500329. A duplicate copy of this form is enclosed.

Date: 31 March 2004

Respectfully submitted,



Jeffrey W. Rennecker  
Attorney For Applicant  
Registration No. 40,784

Agouron Pharmaceuticals, Inc./A Pfizer Company  
Patent Department  
10777 Science Center Drive  
San Diego, California 92121  
Phone: (858) 622-8807  
Fax: (858) 678-8233

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PTO.SB/08A (04-03)

Approved for use through 04/30/03. OMB 0651-0031

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Substitute for form 1449/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

### Complete if Known

Application Number	10/776,568
Filing Date	February 10, 2004
First Named Inventor	Carolyn Petersen, et al.
Art Unit	Not yet assigned
Examiner Name	Not yet assigned
Attorney Docket Number	PC25699A



## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	Cite No. <sup>1</sup>	DOCUMENT NUMBER	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup>			
	AA	5,484,926	02-16-1996	Agouron Pharmaceuticals, Inc.	
	AB	5,952,343	09-14-1999	Agouron Pharmaceuticals, Inc.	
	AC	6,162,812	12-19-2000	Agouron Pharmaceuticals, Inc.	

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>5</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				

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DATE CONSIDERED:

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

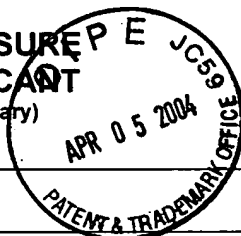
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. Send to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Attorney Docket Number	PC25699A

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	AD	AARNOUTSE, R.E., et al., "Pharmacokinetics, Food Intake Requirements and Tolerability of Once-Daily Combinations of Nelfinavir and Low-Dose Ritonavir in Healthy Volunteers," <i>Br J Clin Pharmacol</i> , 2002, 115-125, Vol. 55.	
	AE	BURGER, David M., et al., "Therapeutic Drug Monitoring (TDM) of Nelfinavir (NFV) 1250 mg BID in Treatment-Naïve Patients Improves Therapeutic Outcome After 1 Year; Result from Athena," <i>2<sup>nd</sup> International Workshop on Clinical Pharmacology of HIV Therapy</i> , 2001, Abstract 6.2b, The Netherlands.	
	AF	KUROWSKI, M., et al., "Limited Effect of Food Composition on the Pharmacokinetics of Nelfinavir Administered Twice Daily," <i>Eur J. Med. Res.</i> , 2002, 453-456, Vol. 7.	
	AG	LENHARD, James M., et al., "Dietary Fat Alters HIV Protease Inhibitor-Induced Metabolic Changes in Mice," <i>American Society for Nutritional Sciences</i> , 2000, 2361-2366.	
	AH	PHYSICIAN'S DESK REFERENCE (PDR) "Entry for Viracept nelfinavir," 2001.	
	AI	PETERSEN, C., et al., "Pharmacokinetics of Nelfinavir (Viracept 250 mg tablet): Effect of Food Intake on Single-dose PK Parameters," <i>10<sup>th</sup> Conference on Retroviruses and Opportunistic Infections Abstract 544</i> , 2003, Boston, MA.	
	AJ	QUART, BD, et al., "Phase I Safety, Tolerance, Pharmacokinetics and Food Effect Studies of AG1343 – a Novel Protease Inhibitor," <i>Natl Conf Hum Retroviruses Relat Infect (2<sup>nd</sup>)</i> , 1995, 167.	
	AK	SHETTY, Bhasker V., et al., "Preclinical Pharmacokinetics and Distribution to Tissue of AG1343, an Inhibitor of Human Immunodeficiency Virus Type 1 Protease," <i>Antimicrobial Agents and Chemotherapy</i> , 1996, 110-114, Vol. 40, No. 1.	

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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. Send to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.